

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Unit : 3731
Examiner : Gwen G. Phanijphand
Serial No. : 09/917,385
Filed : 7/27/01
Inventor : Lisa A.G. Tweardy

22469
PATENT TRADEMARK OFFICE

Docket No.: 1461-R-00

Title : CERAMIC-TIPPED
: SKULL PINS Confirmation No.: 9974

SUPPLEMENTAL DECLARATION OF LISA A. G. TWEARDY

Lisa A. G. Tweardy makes the following declaration:

1. I hereby restate and incorporate by reference, my declaration dated July 14, 2003, which was filed in the above-captioned case.
2. Through scientific experimentation, the rounded pin tip having a radius in the range of about 0.025 - 0.075 mm claimed in application no. 09/917,385 was determined to provide necessary pin strength while allowing penetration into bone.
3. Pin tips must be designed to withstand insertion loads ranging from approximately 100 - 200 lbf and tractions loads of up to 200 pounds.
4. Mechanical tests were performed which simulated maximum mechanical loading in normal clinical use. These results demonstrated that the pin tips of radii less than 0.025 mm could not withstand insertion loads ranging from approximately 100 - 200 lbf and tractions loads of up to 200 pounds.
5. The mechanical tests further demonstrated that pin tips having radii less than 0.025 mm broke when inserted into or removed from bone.
6. Pins with radii greater than 0.075 mm do not provide suitable bone penetration.
7. Electrical testing was performed using apparatus and fixturing intended to determine the complex impedance as an intrinsic material property. The primary conclusion was that the pins fabricated of non-insulating materials did not provide the high values of complex impedance of pins made of insulating material across a wide range of frequencies. This means that the pins fabricated of non-insulating material are not effective barriers to the passage of electromagnetic energy under the operating conditions of the MRI.

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements are made with knowledge that willful false statements so made are punishable by fine or imprisonment, or both; under 18 U.S.C. § 1001, and that such willful and false statements may jeopardize the validity of the application or any patent issuing thereon.

Dated: 2/21/04

Lisa Tweardy